# General

## Guideline Title

Best evidence statement (BESt). Evaluation of heavy menstrual bleeding and menorrhagia in young menstruating females.

## Bibliographic Source(s)

Cincinnati Children's Hospital Medical Center. Best evidence statement (BESt). Evaluation of heavy menstrual bleeding and menorrhagia in young menstruating females. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2011 Feb 18. 10 p. [14 references]

## Guideline Status

This is the current release of the guideline.

# Recommendations

## Major Recommendations

The strength of the recommendation (strongly recommended, recommended, and no recommendation) and the quality of evidence (1a-5b) are defined at the end of the "Major Recommendations" field.

Heavy Menstrual Bleeding

1. It is recommended, for young females being seen for heavy menstrual bleeding, that a history including specific items (see attachment 1 in the original guideline document) and the pictorial blood assessment chart (PBAC) (see attachment 2 in the original guideline document) score be used at the initial visit to identify those who may have a bleeding disorder (Philipp et al., 2008 [3a]; Local Consensus [5]; National Institute for Health and Clinical Excellence [NICE], 2007 [5a]; Demers et al., 2005 [5a]; New Zealand Guidelines Group, 1999 [5a]).
2. It is recommended, for young females being seen for heavy menstrual bleeding, that a complete blood count (CBC) with platelets be obtained to assess for potential anemia (Hurskainen et al., 2007 [5a]; NICE, 2007 [5a]; Kaiser Permanente, 2006 [5a]; Demers et al., 2005 [5a]; New Zealand Guidelines Group, 1999 [5a]).
   Note: In young females a pelvic examination is not likely to be useful due to the rare presence of pathology in this age group (New Zealand Guidelines Group, 1999 [5a]).
3. It is recommended for young females being seen for heavy menstrual bleeding who screen positive for possible bleeding disorder in recommendation #1, that a coagulation screen be conducted (NICE, 2007 [5a]; Kaiser Permanente, 2006 [5a]; Demers et al., 2005 [5a]; New Zealand Guidelines Group, 1999 [5a]).

Menorrhagia

4. It is recommended, for otherwise healthy young females being seen for menorrhagia, that the following laboratory and imaging tests not be

routinely conducted:

- Ferritin
- Female hormone testing
- Thyroid testing
- Endometrial biopsy
- Magnetic resonance imaging (MRI)
- Dilation and curettage
- Hysteroscopy

(NICE, 2007 [5a]; New Zealand Guidelines Group, 1999 [5a]).

5. It is recommended, for young females being seen for menorrhagia, that a menorrhagia-specific quality of life questionnaire be administered at baseline to guide initial management, and periodically to measure response to treatment (see attachment 3 in the original guideline document) (Lukes et al., 2010 [2a]; Winkler, 2001 [3a]).
   Note: General quality of life questionnaires are not helpful in managing women with menorrhagia (Clark et al., 2002 [1a]; Jones, Kennedy, & Jenkinson, 2002 [1a]; Habiba et al., 2010 [2a]; Jenkinson, Peto, & Coulter, 1996 [2a]).

Definitions:

Table of Evidence Levels

| Quality Level | Definition |
|---|---|
| 1a† or 1b† | Systematic review, meta-analysis, or meta-synthesis of multiple studies |
| 2a or 2b | Best study design for domain |
| 3a or 3b | Fair study design for domain |
| 4a or 4b | Weak study design for domain |
| 5 or 5a or 5b | Other: General review, expert opinion, case report, consensus report, or guideline |

†a = good quality study; b = lesser quality study

Table of Recommendation Strength

| Strength | Definition |
|---|---|
| "Strongly recommended" | There is consensus that benefits clearly outweigh risks and burdens (or vice-versa for negative recommendations). |
| "Recommended" | There is consensus that benefits are closely balanced with risks and burdens. |
| No recommendation made | There is lack of consensus to direct development of a recommendation. |
| Dimensions: In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below. | |
| 1. Grade of the Body of Evidence (see note above)<br>2. Safety/Harm<br>3. Health benefit to the patients (direct benefit)<br>4. Burden to patient of adherence to recommendation (cost, hassle, discomfort, pain, motivation, ability to adhere, time)<br>5. Cost-effectiveness to healthcare system (balance of cost/savings of resources, staff time, and supplies based on published studies or onsite analysis)<br>6. Directness (the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome])<br>7. Impact on morbidity/mortality or quality of life | |

## Clinical Algorithm(s)

None provided

# Scope

## Disease/Condition(s)

- Heavy menstrual bleeding
- Menorrhagia

## Guideline Category

Evaluation

Screening

## Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Pediatrics

## Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

- To evaluate, among young menstruating females presenting with complaints of heavy or prolonged menstrual bleeding, what subjective and objective initial evaluation provides sufficient information for designation of menorrhagia and differentiation of those with and without bleeding disorders such as von Willebrand disease
- To evaluate, among young menstruating females diagnosed with menorrhagia, what tool/instrument/questionnaire/inventory provides useful menorrhagia-related quality of life outcome information that is practical for use in outpatient clinic setting for measuring baseline and treatment response over time

## Target Population

Menstruating females less than 25 years of age

## Interventions and Practices Considered

Heavy Menstrual Bleeding

1. History and the pictorial blood assessment chart (PBAC) score
2. Complete blood count (CBC) with platelets
3. Coagulation screen, if applicable

Menorrhagia

Menorrhagia-specific quality of life questionnaire

Note: Pelvic examination, laboratory and imaging tests (ferritin, female hormone testing, thyroid testing, endometrial biopsy, magnetic resonance imaging [MRI], dilation and curettage, hysteroscopy) and general quality of life questionnaires were considered, but not recommended.

## Major Outcomes Considered

- Accurate designation of menorrhagia and differentiation of those with and without bleeding disorders such as von Willebrand disease
- Menorrhagia-related quality of life outcome information

# Methodology

## Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

## Description of Methods Used to Collect/Select the Evidence

Search Strategy

1. Initial Search
    - Databases: OVID Medline, Cochrane and National Guideline Clearinghouse
    - Dates 1996 through September 2010
    - Search terms (OVID):
      (guideline or meta analysis or practice guidelines or systematic review).pt. or "the cochrane library".jn. or "cochrane database of systematic reviews".jn.

    AND

    menorrhagia.mp. or exp heavy menstrual bleeding or abnormal uterine bleeding

    - Search terms (National Guideline Clearinghouse): menorrhagia or "heavy menstrual bleeding" or "abnormal uterine bleeding"
    - Limit: English language
2. Specific search on questionnaires for menorrhagia
    - Databases: OVID Medline
    - Dates 1996 through September 2010
    - Search terms:
      (menorrhagia.mp. or exp Menorrhagia/) AND outcomes.mp. AND (questionnaire.mp. or *Questionnaires/) NOT (hysterectomy.mp. or ablat$.ti. or surger$.ti.)
    - Limit: English language
3. Additional articles identified by clinicians

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Table of Evidence Levels

| Quality Level | Definition |
|---|---|
| 1a† or 1b† | Systematic review, meta-analysis, or meta-synthesis of multiple studies |
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## Methods Used to Analyze the Evidence

Systematic Review

## Description of the Methods Used to Analyze the Evidence

The recommendations are based upon synthesized evidence from 5 clinical practice guidelines. The guidelines, developed by clinical experts and based upon evidence identified in a comprehensive and systematic literature search, identify assessment parameters used to diagnose menorrhagia. None of the guidelines had clear evidence-based recommendations for evaluation of menorrhagia in young females. These guidelines were appraised using the AGREE (Appraisal of Guidelines for Research and Evaluation) instrument and the results are presented in the original guideline document.

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

Not stated

## Rating Scheme for the Strength of the Recommendations

Table of Recommendation Strength

| Strength | Definition |
|---|---|
| | |

| Strength | Definition |
| --- | --- |
| "Strongly recommended" | There is consensus that benefits clearly outweigh risks and burdens (or vice-versa for negative recommendations). |
| "Recommended" | There is consensus that benefits are closely balanced with risks and burdens. |
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Dimensions: In determining the strength of a recommendation, the development group makes a considered judgment in a consensus process that incorporates critically appraised evidence, clinical experience, and other dimensions as listed below.

1. Grade of the Body of Evidence (see note above)
2. Safety/Harm
3. Health benefit to the patients (direct benefit)
4. Burden to patient of adherence to recommendation (cost, hassle, discomfort, pain, motivation, ability to adhere, time)
5. Cost-effectiveness to healthcare system (balance of cost/savings of resources, staff time, and supplies based on published studies or onsite analysis)
6. Directness (the extent to which the body of evidence directly answers the clinical question [population/problem, intervention, comparison, outcome])
7. Impact on morbidity/mortality or quality of life

## Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

## Method of Guideline Validation

Peer Review

## Description of Method of Guideline Validation

Reviewed against quality criteria by 2 independent reviewers.

# Evidence Supporting the Recommendations

## References Supporting the Recommendations


Clark TJ, Khan KS, Foon R, Pattison H, Bryan S, Gupta JK. Quality of life instruments in studies of menorrhagia: a systematic review. Eur J Obstet Gynecol Reprod Biol. 2002 Sep 10;104(2):96-104. [44 references] PubMed

Demers C, Derzko C, David M, Douglas J, Society of Obstetricians and Gynecologists of Canada. Gynaecological and obstetric management of women with inherited bleeding disorders. J Obstet Gynaecol Can. 2005 Jul;27(7):707-32. PubMed

Habiba M, Julian S, Taub N, Clark M, Rashid A, Baker R, Szczepura A. Limited role of multi-attribute utility scale and SF-36 in predicting management outcome of heavy menstrual bleeding. Eur J Obstet Gynecol Reprod Biol. 2010 Jan;148(1):81-5. PubMed

Hurskainen R, Grenman S, Komi I, Kujansuu E, Luoto R, Orrainen M, Patja K, Penttinen J, Silventoinen S, Tapanainen J, Toivonen J. Diagnosis and treatment of menorrhagia. Acta Obstet Gynecol Scand. 2007;86(6):749-57. PubMed

Jenkinson C, Peto V, Coulter A. Making sense of ambiguity: evaluation in internal reliability and face validity of the SF 36 questionnaire in women presenting with menorrhagia. Qual Health Care. 1996 Mar;5(1):9-12. PubMed

Jones GL, Kennedy SH, Jenkinson C. Health-related quality of life measurement in women with common benign gynecologic conditions: a systematic review. Am J Obstet Gynecol. 2002 Aug;187(2):501-11. [86 references] PubMed

Kaiser Permanente. Chronic abnormal uterine bleeding in non-gravid women. Pasadena (CA): Kaiser Permanente Southern California; 2006.

Lukes AS, Moore KA, Muse KN, Gersten JK, Hecht BR, Edlund M, Richter HE, Eder SE, Attia GR, Patrick DL, Rubin A, Shangold GA. Tranexamic acid treatment for heavy menstrual bleeding: a randomized controlled trial. Obstet Gynecol. 2010 Oct;116(4):865-75. PubMed

National Institute for Health and Clinical Excellence (NICE). Heavy menstrual bleeding. London (UK): National Institute for Health and Clinical Excellence (NICE); 2007. 192 p.

New Zealand Guidelines Group. An evidence-based guideline for the management of heavy menstrual bleeding. Working Party for Guidelines for the Management of Heavy Menstrual Bleeding. N Z Med J. 1999 May 28;112(1088):174-7. PubMed

Philipp CS, Faiz A, Dowling NF, Beckman M, Owens S, Ayers C, Bachmann G. Development of a screening tool for identifying women with menorrhagia for hemostatic evaluation. Am J Obstet Gynecol. 2008 Feb;198(2):163.e1-8. PubMed

Winkler UH. The effect of tranexamic acid on the quality of life of women with heavy menstrual bleeding. Eur J Obstet Gynecol Reprod Biol. 2001 Dec 1;99(2):238-43. PubMed

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Women with undiagnosed bleeding disorders who present with heavy menstrual bleeding benefit from screening as a result of being identified for further testing and evaluation. Adherence to these recommendations will decrease unnecessary pelvic examinations and unnecessary diagnostic studies in menstruating young females with menorrhagia, and will direct appropriate treatment to prevent anemia, transfusions, and hospital admissions in those with bleeding disorders.

### Potential Harms

Adherence to the recommendations carries minimal risks or burden to patients which includes venipunctures, giving family medical and gynecological history, and completing quality of life questionnaires.

## Qualifying Statements

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This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

# Implementation of the Guideline

## Description of Implementation Strategy

Applicability Issues

Measures that are proposed to be audited:

- Percentage of females presenting to the Teen Health Center with "vaginal bleeding" as chief complaint who had all three of the following assessments completed: complete blood count (CBC), Menorrhagia questionnaire and pictorial blood assessment chart (PBAC) assessment.
- Percentage of females presenting to the Teen Health Center with "vaginal bleeding" as the chief complaint, and with positive results on a Menorrhagia Assessment who also had bleeding disorder workup conducted (CBC with platelets, coagulation screen).
- Percentage of females presenting to the Teen Health Center with "vaginal bleeding" as the chief complaint who were hospitalized within 30 days of most recent outpatient visit as a result of heavy menstrual bleeding.

## Implementation Tools

Chart Documentation/Checklists/Forms

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

## IOM Care Need

Getting Better

## IOM Domain

Effectiveness

# Identifying Information and Availability

## Bibliographic Source(s)

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## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2011 Feb 18

## Guideline Developer(s)

Cincinnati Children's Hospital Medical Center - Hospital/Medical Center

## Source(s) of Funding

Cincinnati Children's Hospital Medical Center

## Guideline Committee

Not stated

## Composition of Group That Authored the Guideline

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## Financial Disclosures/Conflicts of Interest

Not stated

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available from the Cincinnati Children's Hospital Medical Center .

Print copies: For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Cincinnati Children's Hospital Medical Center Health James M. Anderson Center for Health Systems Excellence at EBDMInfo@cchmc.org.

## Availability of Companion Documents

The following are available:

- Table of evidence levels. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 May 7. 1 p. Available from the Cincinnati Children's Hospital Medical Center .
- Grading a body of evidence to answer a clinical question. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 May 7. 1 p. Available from the Cincinnati Children's Hospital Medical Center .
- Judging the strength of a recommendation. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 May 7. 1 p. Available from the Cincinnati Children's Hospital Medical Center .

Additionally, the original guideline document contains screening tools for assessment of heavy menstrual bleeding and menorrhagia.

Print copies: For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Cincinnati Children's Hospital Medical Center Health James M. Anderson Center for Health Systems Excellence at EBDMInfo@cchmc.org.

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on August 26, 2011.

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